

K955247

**510(k) Summary
for
Olympus KD Series of Sphincterotome**

APR 30 1996

Device Name: Olympus KD Sphincterotome

Common/Usual Name: Sphincterotome

Classification Name: Endoscope Electrosurgical Unit and Accessories
21 CFR 876.4300

Predicate Devices: Olympus KD-1/2 pre-Amendment Diathermic Cutters, Olympus PK Papillotomy Knives, and Olympus KD-6G Sphincterotomes

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Summary Preparation Date: 6 October 1995

Statement of Intended Use: The KD sphincterotomes and the predicated devices are all designed specifically to perform endoscopic sphincterotomy of the papilla of Vater

Device Description: The KD sphincterotomes and the predicated devices are all designed specifically to perform endoscopic sphincterotomy of the papilla of Vater. The KD sphincterotomes consist of three primary parts: a proximal end control handle, a flexible catheter-like tube, and a distal end knife wire. The catheter shaft contains a thin steel wire that exits the catheter shaft for a short length and then re-enters the shaft. The exposed wire is referred to as the knife wire. The knife wire may be either tensioned or pushed to position the wire for cutting. This is accomplished by maneuvering the control handle slider accordingly. The detachable control handle contains the electrical connections which permit the knife wire to be connected to an electrosurgical generator.